

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ENDO PHARMACEUTICALS INC. and  
PENWEST PHARMACEUTICALS CO.,

Plaintiffs,

v.

IMPAX LABORATORIES, INC.,

Defendant.

C. A. No. 08-463 GMS

**ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS  
OF DEFENDANT IMPAX LABORATORIES, INC.**

Defendant and Counterclaim Plaintiff Impax Laboratories, Inc. (“Impax”) hereby answers the numbered paragraphs of the Complaint of Plaintiffs Endo Pharmaceuticals (“Endo”) and Penwest Pharmaceuticals (“Penwest”) as follows:

1. Impax admits that Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317. Impax admits that Endo sells Opana ER. Impax is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph and, on that basis, denies them.

2. Impax admits that Penwest is a Washington corporation, having its principal place of business at 39 Old Ridgebury Road, Suite 11, Danbury, Connecticut 06810-5120. Impax is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph and, on that basis, denies them.

3. Admit.

4. Impax admits it manufactures generic drug products. The word “throughout” is vague and, on that basis, Impax denies the remaining allegations in this paragraph.

5. This paragraph does not require an answer.

6. Admit.

7. Impax admits that U.S. Patent No. 5,662,933 (the “’933 Patent”) purports on its

face to have been issued by the U.S. Patent and Trademark Office (“PTO”) on September 2, 1997, to Edward Mendell Co., Inc., as assignee. Impax is without knowledge or information sufficient to form a belief as to the second sentence in this paragraph and, on that basis, Impax denies the remaining allegations in this paragraph.

8. Impax admits that U.S. Patent No. 5,958,456 (the “’456 Patent”) purports on its face to have been issued by the PTO on September 28, 1999, to Edward Mendell Co., Inc., as assignee. Impax is without knowledge or information sufficient to form a belief as to the second sentence in this paragraph and, on that basis, Impax denies the remaining allegations in this paragraph.

9. Impax is without knowledge or information sufficient to form a belief as to the allegations in this paragraph and, on that basis, denies them.

10. Impax admits that new drug application (“NDA”) No. 21-610 covers Opana ER and was approved on June 22, 2006. The NDA speaks for itself and the remaining allegations in this paragraph therefore do not require a response.

11. Impax admits that the Food and Drug Administration’s Orange Book lists the ’933 and ’456 Patents as covering OPANA ER tablets. Impax is without knowledge or information sufficient to form a belief as to the remaining allegations in this paragraph and, on that basis, denies them.

12. Impax denies these allegations as to the word “purporting” because Impax did submit an Abbreviated New Drug Application (“ANDA”). Otherwise, the allegations in this paragraph are admitted.

13. Admit.

14. Admit.

15. Impax admits that the FDA sent Impax a letter dated December 12, 2007 advising Impax that it had determined that it had received ANDA 79-087 as acceptable for filing on November 23, 2007. Impax admits that the letter requested that Impax provide notice and information required by 21 U.S.C. § 355(j)(2)(B)(i). Impax denies the remaining allegations in

this paragraph.

16. Admit.

17. Admit.

18. Admit.

19. Impax admits that on January 25, 2008, Endo and Penwest filed a complaint against Impax in the District of Delaware alleging patent infringement of the '456 and '933 Patents and that this matter is Civil Action No. 08-057 (GMS) and is currently pending in this district. Impax denies the remaining allegations in this paragraph.

20. Admit.

21. Admit.

22. Admit.

### **COUNT I**

#### **INFRINGEMENT OF THE '456 PATENT**

23. This paragraph does not require a response.

24. Denied.

25. Denied.

26. Impax admits that the Paragraph IV certification in its ANDA references the '456 Patent. The allegation that "Impax was aware of the existence of the '456 patent as . . ." is vague as to timing and on that basis, is denied. The remaining allegations are denied.

### **COUNT II**

#### **INFRINGEMENT OF THE '933 PATENT**

27. This paragraph does not require a response.

28. Denied.

29. Denied.

30. Impax admits that the Paragraph IV certification in its ANDA references the '933 Patent. The allegation that "Impax was aware of the existence of the '933 patent as . . ." is vague as to timing and on that basis, is denied. The remaining allegations are denied.

**AFFIRMATIVE DEFENSES**

**FIRST AFFIRMATIVE DEFENSE**

**(Prosecution History Estoppel)**

31. An additional basis of non-infringement is that statements, representations, admissions, and amendments made to the United States Patent and Trademark Office during the prosecution of the applications which matured into the '456 Patent and the '933 Patent, and/or their parent applications, as well as the prior art, estops Endo and Penwest from asserting that the claims of said patents are infringed by Impax's ANDA 79-087, including all amendments thereto ("Impax's oxymorphone ANDA").

**SECOND AFFIRMATIVE DEFENSE**

**(Invalidity)**

32. The '456 Patent and the '933 Patent and each of the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description and indefiniteness in accordance with 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, or are invalid pursuant to the judicial doctrine barring double-patenting.

**THIRD AFFIRMATIVE DEFENSE**

**(Inequitable Conduct)**

33. The '456 Patent and the '933 Patent and each of the claims thereof are unenforceable because of inequitable conduct before the PTO.

34. From the time of the filing of the '008 application through to the issuance of the '933 Patent, and from the time of the filing of the '496 application through to the issuance of the '456 Patent, each of the Patentees had a duty of candor and good faith to disclose to the PTO all information known to that individual that is material to patentability, pursuant to United States patent laws and regulations, including 37 C.F.R. § 1.56(a).

35. On information and belief, on September 9, 1993, named inventor Anand

Baichwal, his agents and the agents of assignee Penwest, or its predecessor Edward Mendell Co., Inc., filed a patent application, U.S. Patent Application No. 08/118,924 (“’924 application”).

36. On information and belief, on November 3, 1995, named inventors Baichwal and Troy W. McCall, their agents and the agents of assignee Penwest, or its predecessor Edward Mendell Co., Inc. (collectively, “Patentees”), filed a patent application, U.S. Patent Application No. 08/553,008 (“’008 application”). This application was filed as a continuation-in part application claiming priority to the ’924 application. The ’933 Patent issued from the ’008 application.

37. On information and belief, on July 1, 1997, named inventors Baichwal and McCall, their agents and the agents of assignee Penwest, or its predecessor Edward Mendell Co., Inc. (collectively, “Patentees”), filed a patent application, U.S. Patent Application No. 08/886,496 (“’496 application”). This application was filed as a continuation application of the ’008 application and claimed priority to the ’924 application. The ’456 Patent issued from the ’496 application.

38. In a Supplemental Declaration filed during prosecution of the ’008 application and signed by named inventors Baichwal and McCall, the Patentees claimed that the ’008 application was entitled to the benefit of the filing date of the ’924 application under 35 U.S.C. § 120. However, contrary to the express requirements of 35 U.S.C. § 120, the ’008 application and the ’924 application were not co-pending applications. The ’008 application was filed on November 3, 1995, one month after U.S. Patent No. 5,455,046 (the “’046 Patent”) had issued from the ’924 application. Accordingly, the ’008 application is not entitled to the benefit of the filing date of the ’924 application. On information and belief, the Patentees misrepresented the priority date to which the ’008 application is entitled with intent to deceive the PTO.

39. The Patentees filed the ’496 application as a continuation application of the ’008 application, thereby claiming entitlement to the priority date of the ’008 application, which claimed entitlement to the filing date of the ’924 application. However, because the ’008 application is not entitled to the filing date of the ’924 application, the ’496 application is not

entitled to this priority date either. On information and belief, the Patentees misrepresented the priority date to which the '496 application is entitled with intent to deceive the PTO.

40. On February 5, 2008, the PTO issued a Certificate of Correction that modified Item 63 of the '933 Patent from "Continuation-in-part of Ser. No. 118,924, Sep. 9, 1993, Pat. No. 5,455,046" to "Continuation-in-part of Ser. No. 08/447,236, May 22, 1995, U.S. Pat. No. 5,554,387, which is a division of Ser. No. 118,924, Sep. 9, 1993, Pat. No. 5,455,046." This Certificate of Correction has no effect in the present action because it is invalid and, even if it is found valid, applies only to causes of action arising after its issuance. *See* 35 U.S.C. § 255.

41. On February 5, 2008, the PTO issued a Certificate of Correction that modified the text at bracket 63 of the '456 Patent from "Continuation of application No. 08/553,008, Nov. 3, 1995, Pat. No. 5,662,933, which is a continuation-in-part of application No. 08/118,924, Sep. 9, 1993, Pat. No. 5,455,046" to "Continuation of application No. 08/553,008, Nov. 3, 1995, Pat. No. 5,662,933, which is a continuation-in-part of application No. 08/447,236, May 22, 1995, U.S. Pat. No. 5,554,387, which is a division of application No. 08/118,924, Sep. 9, 1993, Pat. No. 5,455,046." This Certificate of Correction has no effect in the present action because it is invalid and, even if it is found valid, applies only to causes of action arising after its issuance. *See* 35 U.S.C. § 255.

42. On information and belief, the Patentees intentionally failed to disclose to the PTO multiple references that Patentees knew were highly material to the patentability of claims of the '933 and '456 Patents. These non-disclosed patents include at least U.S. Patent Nos. 5,169,639 ("the '639 Patent"); 5,330,761; 5,399,358; 5,399,359; and 5,399,362, each of which covers subject matter similar to the subject matter of the claims of the '933 and '456 Patents. All of these non-disclosed patents issued prior to the filing dates of the '933 and '456 Patents and the Patentees had a duty to disclose their existence during the prosecution of the '933 and '456 Patents. Baichwal, who is named as an inventor on both the '933 and '456 Patents, is a named inventor on all of these non-disclosed patents and each of these non-disclosed patents purports on its face to be assigned to Edward Mendell Co., Inc., Penwest's predecessor.

43. Each of these non-disclosed patents is highly material to the patentability of the claims of the '933 and '456 Patents. For example, during prosecution of the '924 application, the purported parent application of the '933 and '456 Patents, the PTO issued rejections based on two patents related to the non-disclosed '639 Patent: U.S. Patent No. 5,128,143 ("the '143 Patent") and U.S. Patent No. 4,994,276 ("the '276 Patent"). The '143 Patent is the parent of the '639 Patent, and the '276 Patent is the grandparent of the '639 Patent. During prosecution of the '924 application, the PTO rejected all of the pending, non-withdrawn claims of the '924 application for statutory and non-statutory, obviousness-type double patenting over claims 1-24 of the '143 Patent. Similarly, during prosecution of the '924 application, the PTO rejected all of the pending, non-withdrawn claims of the '924 application for statutory and non-statutory, obviousness-type double patenting over claims 1-18 of the '276 Patent. Despite receiving statutory and non-statutory, obviousness-type double patenting rejections over these related patents during prosecution of the '924 purported parent application, the Patentees did not disclose the '639 Patent to the PTO during prosecution of the applications for either the '456 or the '933 Patents.

44. Based on the above-described events, Impax alleges that the Patentees knew of but withheld material prior art from the PTO during the prosecution of the '456 and '933 Patents. On information and belief, the Patentees withheld the subject prior art during the prosecution of the '456 and '933 Patents with the intent to deceive the PTO.

#### **FOURTH AFFIRMATIVE DEFENSE**

##### **(Unclean Hands)**

45. The '456 Patent and the '933 Patent are unenforceable because Endo and/or Penwest have unclean hands.

#### **FIFTH AFFIRMATIVE DEFENSE**

##### **(Dedication to the Public)**

46. The '456 Patent and the '933 Patent are not infringed under the doctrine of equivalents because all embodiments described in the prior patents in the same patent family

and/or in the patents but not claimed by them were dedicated to the public.

### **COUNTERCLAIMS FOR AFFIRMATIVE RELIEF**

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Impax hereby asserts counterclaims against Endo and Penwest as follows:

47. Impax incorporates by reference its responses and allegations set forth in Paragraphs 1 through 46 hereof.

48. As a result of the Plaintiffs' allegations of infringement against Impax and their other actions, an actual controversy exists as to issues of infringement, validity, and enforceability of the '456 and '933 Patents.

### **PARTIES**

49. Counterclaim Plaintiff Impax is a corporation in good standing incorporated under the laws of the State of Delaware, with its principal place of business at 30831 Huntwood Avenue, Hayward, California 94544.

50. On information and belief, Endo is a Delaware corporation, having its principal place of business at 100 Endo Boulevard, Chadds Ford, Pennsylvania 19317.

51. On information and belief, Penwest is a Washington corporation, having its principal place of business at 39 Old Ridgebury Road, Suite 11, Danbury, Connecticut 06810-5120.

### **JURISDICTION AND VENUE**

52. Jurisdiction over this counterclaim is proper pursuant to 28 U.S.C. §§ 1331, 1338, and 2201-2202.

53. Because Endo and Penwest sued Impax for patent infringement in this Judicial District, this Court has personal jurisdiction over Endo and Penwest and venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c).



### **BACKGROUND**

54. An actual controversy exists between Endo and Penwest, on the one hand, and Impax, on the other, concerning the '456 and '933 Patents, which requires a declaration of rights by this Court. This controversy relates to the alleged infringement, validity, and enforceability of the '456 and '933 Patents.

55. Endo and Penwest have asserted ownership and/or control of the '456 and '933 Patents and have sued Impax for allegedly infringing them. Endo has had these patents listed in the Orange Book as covering the drug that is the subject of NDA No. 21-610, which is the reference application for Impax's oxymorphone ANDA. On November 12, 2007, Impax requested that Endo and Penwest provide Impax with a perpetual covenant not to sue for infringement of the '456 and '933 Patents by Impax's oxymorphone ANDA. Endo and Penwest have thus far refused to provide Impax with a covenant not to sue under the '456 and '933 Patents. Rather, Endo and Penwest sued Impax for infringing the '456 and '933 Patents on November 15, 2007, January 25, 2008, and again on July 25, 2008. In a joint press release issued on December 17, 2007, and citing the '456 and '933 Patents, Endo and Penwest stated that they "will continue to pursue all available legal and regulatory avenues in defense of OPANA ER, including enforcement of their intellectual property rights[.]"

### **COUNT I**

#### **(Declaratory Judgment of Non-Infringement of the '456 Patent)**

56. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 55 hereof.

57. Impax has not infringed, is not infringing, and will not infringe any of the claims of the '456 Patent, literally or under the doctrine of equivalents.

58. Impax is entitled to a declaratory judgment that its oxymorphone ANDA does not infringe the '456 Patent.

**COUNT II**

**(Declaratory Judgment of Invalidity of the '456 Patent)**

59. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 58 hereof.

60. The '456 Patent and each of the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description and indefiniteness in accordance with 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, or are invalid pursuant to the judicial doctrine barring double-patenting.

61. Impax is entitled to a declaratory judgment that the '456 Patent is invalid.

**COUNT III**

**(Declaratory Judgment of Unenforceability of the '456 Patent)**

62. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 61 hereof.

63. The '456 Patent and each of the claims thereof are unenforceable because of inequitable conduct before the PTO. The Patentees misrepresented or omitted material information in prosecuting the '456 Patent, and did so with intent to deceive the PTO.

64. Impax is entitled to a declaratory judgment that the '456 Patent is unenforceable.

**COUNT IV**

**(Declaratory Judgment of Non-Infringement of the '933 Patent)**

65. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 64 hereof.

66. Impax has not infringed, is not infringing, and will not infringe any of the claims of the '933 Patent, literally or under the doctrine of equivalents.

67. Impax is entitled to a declaratory judgment that its oxymorphone ANDA does not infringe the '933 Patent.

**COUNT V**

**(Declaratory Judgment of Invalidity of the '933 Patent)**

68. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 67 hereof.

69. The '933 Patent and each of the claims thereof are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including, but not limited to, utility, anticipation, obviousness, lack of enablement, lack of written description and indefiniteness in accordance with 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, or are invalid pursuant to the judicial doctrine barring double-patenting.

70. Impax is entitled to a declaratory judgment that the '933 Patent is invalid.

**COUNT VI**

**(Declaratory Judgment of Unenforceability of the '933 Patent)**

71. Impax realleges and incorporates by reference its responses and allegations set forth in Paragraphs 1 through 70 hereof.

72. The '933 Patent and each of the claims thereof are unenforceable because of inequitable conduct before the PTO. The Patentees misrepresented or omitted material information in prosecuting the '933 patent, and did so with intent to deceive the PTO.

73. Impax is entitled to a declaratory judgment that the '933 Patent is unenforceable.

**PRAYER FOR RELIEF**

WHEREFORE, Impax respectfully requests that this Court enter a Judgment and Order:

A. Dismissing the Complaint, and each count thereof, with prejudice and denying Endo and Penwest any relief whatsoever;

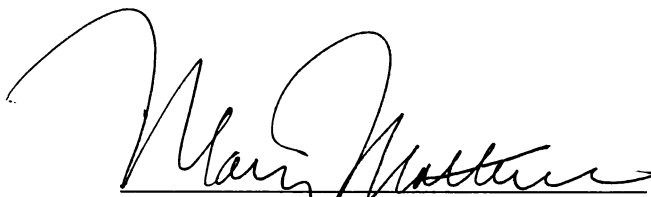
B. Declaring the '456 and '933 Patents to be unenforceable, invalid and/or not infringed by Impax directly, by inducement of infringement, or otherwise;

C. Issuing an injunction restraining Endo and Penwest from enforcing or attempting to enforce the '456 and '933 Patents against Impax, any of Impax's suppliers, or any of Impax's customers or potential customers;

D. Declaring this case to be an exceptional case pursuant to 35 U.S.C. § 285 or otherwise, and that Impax shall be awarded its costs, together with reasonable attorneys' fees and all of its expenses for defending this suit;

E. Awarding Impax pre-judgment and post-judgment interest as allowed by law;

F. Awarding Impax any such other and further relief as the Court may deem just and proper.



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